

The process of the present invention is predicated on the discovery by Applicant of a generic class of compounds known as RECOGNINS, which are related, inter alia, to the recognition and learning functions in cells, and which are useful in the diagnosis and treatment of cancer.

Specific compounds within the class of RECOGNINS include ASTROCYTIN, which can be derived from brain tumor cells; MALIGNIN, which can be derived from artificial brain tumor cells grown in culture; RECOGNIN L, which can be derived from artificial lymphoma tumor tissue grown in culture; and RECOGNIN M, which can be derived from artificial mammary tumor cells grown in culture. These compounds, derived from cancerous tumor cells, can also be referred to as "cancer-RECOGNINS" to distinguish them from certain RECOGNINS which can be derived, as discovered by applicant, from "normal", i.e., non-cancerous cells.

Each of the class of RECOGNINS can be used to produce its anti-body, e.g., the compound produced in an animal in response to one of the RECOGNINS. Thus, the compounds anti-ASTROCYTIN, anti-MALIGNIN, anti-RECOGNIN L and anti-RECOGNIN M can be produced. In one means for producing these anti-bodies, the particular RECOGNIN is complexed with an inert carrier material. This complex, known as TARGET reagent, is then mixed, e.g., with human sera to produce the particular anti-RECOGNIN, the inert carrier merely facilitating its isolation. The anti-RECOGNIN produced in this manner is referred to as a TAG product. Other means are also available for producing and/or isolating a particular anti-RECOGNIN.

One of the primary utilities of RECOGNINS is their use as a cancer diagnostic tool. In one such method, the first true serum diagnostic method for cancer detection, the values or amounts of TAG products produced in human serum from, e.g., MALIGNIN or ASTROCYTIN-based TARGET are elevated and therefore used, in a correlative manner, to detect a variety of cancerous tumors.

A second method of cancer detection, to which the present invention is directed, is predicated on applicant's discovery of the unique ability of the anti-bodies to cancer-RECOGNINS, i.e., anti-cancer-RECOGNINS, to preferentially attach to cancerous tumor cells in a cell collection. Thus, by means of suitable detection devices (e.g., fluorescent dyes, radio-emitting compounds) the presence of cancerous tumor cells can be detected.

Before turning to the specifics of the claims presented for examination, it should be noted that the subject matter discussed above is the subject of a number of patent applications filed by applicant as well as numerous technical publications. In this connection, the Examiner's attention is directed to applicant's allowed patent applications Ser. Nos. 852,198 and 852,200, which were examined in Group 125, and which are directed, inter alia, to the RECOGNIN MALIGNIN, its preparation, anti-MALIGNIN, MALIGNIN-based TARGET and a serum diagnostic test utilizing MALIGNIN-based products. Also of record in these applications are Declarations of applicant reporting on various testing employing RECOGNINS performed by noted researchers in the field and various publications of applicant and others in this area. Should the Examiner desire, these materials can be made of record in the present application.

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In addition, applicant has submitted herewith copies of more recent publications or pending publications in this field. The Examiner will note that the publication from The Lancet, May 5, 1979, p. 987; the Harris, et al. paper accepted for publication by Academic Press; and the Redmond, et al. paper submitted for publication to the Federation of Associated Societies of Experimental Biology relate in particular to the subject matter of the present application.

Claim 13 of the present application describes a method for the detection of cancerous tumor cells in a cell collection wherein an "anti-cancer-RECOGNIN product" is applied to the cell collection. Thus, this product is the anti-body to a "cancer-RECOGNIN". The reason why the claim is phrased in terms of an anti-cancer-RECOGNIN product is because, as described in detail in the specification, such a "product" may be either intact anti-cancer-RECOGNIN, e.g., as obtained by reaction of a cancer RECOGNIN (optionally complexed with an inert carrier) with human serum or a purified fraction of anti-cancer-RECOGNIN (see p. 40a, line 29 et. seq. of the present specification). The terms RECOGNIN and anti-RECOGNIN are completely defined in the specification and are understood in the art such that there is no indefiniteness in the claims.

Claim 14 relates to a specific cancer RECOGNIN, i.e., MALIGNIN and, in the same manner as claim 13, calls for application of "an anti-MALIGNIN product" to the cell collection. MALIGNIN is a specific substance extensively defined in the specification herein.

Claim 15 relates to one particular method for detecting cancerous tumor cells through the use of a fluorescein dye. In this method, an anti-MALIGNIN product is applied to the cell collection to achieve preferential attachment of such product

to cancerous cells in the collection. In order to obtain a visible (i.e., fluorescence) signal, fluorescein is conjugated to a material which will itself "attach" to the anti-MALIGNIN product which has attached to the cancer cells. Such a product is known as anti-(anti-MALIGNIN). Such a product is defined in the specification herein and merely consists of a product which will "recognize" the species from which the anti-MALIGNIN product is produced. Thus, for example, if the anti-MALIGNIN product is produced from human serum, the anti-(anti-MALIGNIN) must be one derived in response to a human antigen, e.g., rabbit anti-human serum.

Claim 18 merely recites that the anti-MALIGNIN product is produced by reaction of anti-MALIGNIN with MALIGNIN, e.g., by using MALIGNIN to obtain or extract anti-MALIGNIN from a particular source, taking advantage of the specific affinity of MALIGNIN for its antibody. Claims 19 and 20 relate to using MALIGNIN complexed with an inert carrier to accomplish the production of anti-MALIGNIN, the carrier facilitating isolation of the anti-body.

Claim 21 relates to the earlier-mentioned purification or fractionation of anti-MALIGNIN to obtain anti-MALIGNIN products for use in the method of the present invention.

Claims 23 through 26 relate to the attachment of signal-emitting means either directly or indirectly to the anti-MALIGNIN product.

Claim 29 is of the same scope as claim 14 but adds a definition of MALIGNIN commensurate with that in the allowed claims of applicant's application Serial No. 852,198.

Claims 30 and 31 relate to a method of purifying intact anti-MALIGNIN and the purification products thereof.

In view of the foregoing analysis, applicant respectfully urges that the terms utilized in the claims to describe his inventive method are in fact of definite scope in that the specification contains ample definition thereof. The field of applicant's invention, and hence the words utilized to define it, are admittedly new. However, it is axiomatic that an applicant can be his own lexicographer so long as the terms employed are defined and do not render the claim ambiguous or misleading. It is submitted that the unquestioned use of the various names and terms assigned by applicant to his novel class of compounds by researchers who have published in this art is telling testimony of the fact that these terms, in view of the definitions and explanations provided in the application, are of understandable scope.

With regard to the Examiner's requirement that the color photographs submitted as Figs. 2, 3a and 3b be cancelled, along with reference thereto in the specification, applicant respectfully requests reconsideration. The present invention is predicated, in part, upon the selective staining of cancer cells a noticeable, detectable color. Although applicant appreciates that the Patent and Trademark Office cannot produce the photographs in color, it is considered proper that these photographs be made a permanent part of the record of this application as evidence of the utility of the invention. Applicant would, of course, be willing to submit corresponding black and white photographs or drawings as illustrating, as best as possible, the staining of the various cell collections.

In view of the amendment and remarks herein, applicant respectfully urges that the claims presented for examination are in condition for allowance. Early, favorable notice to this effect is earnestly solicited.

Respectfully submitted,

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